[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Photosensitizing Antibody-Fluorophore Conjugates for Photo-Immunotherapy

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a worldwide exclusive evaluation option license, to practice the inventions embodied in US patent application 13/180,111, filed July 11, 2011 (HHS Reference# E-205-2010/0-US-02), originated from provisional application 61/363,079 filed July 09, 2010, and entitled "Photosensitizing Antibody Fluorophore Conjugates for Photo-Immunotherapy" to Aspyrian Therapeutics, Inc., a company incorporated under the laws of the State of Delaware, having its headquarters in San Diego, California. The United States of America is the assignee of the rights of the above inventions.

The field of use may be limited to "use of photosensitizing antibody-fluorophore conjugate for imaging and photo-immunotherapy of cancer" and may be further limited to certain types of cancer and/or specific platforms.

Upon the expiration or termination of the exclusive evaluation option license, Aspyrian Therapeutics, Inc. will have the right to execute an exclusive worldwide patent commercialization

license which will supersede and replace the exclusive evaluation option license with the same field of use.

DATE: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before [Insert date fifteen (15) days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Uri Reichman, Ph.D., M.B.A, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4616; Facsimile: (301) 402-0220; E-mail: Reichmau@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The present technology provides a novel method for cancer therapy which may offer improved specificity and sensitivity in cancer treatment. The method is based on molecular targeting. More specifically, it is based on photoimmunotherapy (PIT). The therapeutic agent is a targeted photosensitizer composed of a tumor specific antibody conjugated to IR700 dye, where the dye is sensitive to a near infrared light. Upon administration of the conjugated antibody to a subject, it specifically binds to the targeted cancerous tissue. Upon subsequent irradiation with a near infrared light, the dye releases energy that leads to the killing of the targeted cells. The concept was proven by the inventors *in vitro* and *in vivo* with mouse models, using humanized anti-HER1 (Panitumumab, for colon cancer), anti-HER2 (Trastuzumab, for breast cancer) and anti-PSMA antibody (huJ591, for prostate cancer). Targeted

cells were completely killed while normal cells were not noticeably affected. The technology provides also for wearable LED systems that can be used to irradiate the photosensitizer.

The prospective exclusive evaluation option license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive evaluation option license may be granted unless, within fifteen (15) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

February 13, 2012
Date

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Richard U. Rodriguez, M.B.A.
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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